

Prior Notice Questions

02N-0278

REF 2



U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

**Instructions: Please print one question per sheet.
Include your name and affiliation.**

QUESTIONS FOR PANELISTS

Name:

Affiliation:

What is the prior notice requirement for
foods imported to a foreign trade zone
within the U.S.?

John Cox - The Rodent Group



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QUESTIONS FOR PANELISTS

Name:

Affiliation:

~~What is~~

Are
~~the~~ bonded public cold storage

facilities considered "secure"

in cases where,
facilities ~~should~~ an entry

has been inadequately processed

for prior notice requirements



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QUESTIONS FOR PANELISTS

Name:

Affiliation:

For air transport, the ACS
entry number is generally not
available by noon of the day
before entry. How would prior
notice be handled in such a
situation?



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QUESTIONS FOR PANELISTS

Name:

Affiliation:

Currently US Customs requires full
manifest into 24 hr prior to cargo
being loaded onto the ship in a foreign port
why isn't this good enough for prior notice



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QUESTIONS FOR PANELISTS

Name:

Affiliation:

U.S. Customs requires that entry ~~to~~ for
air shipments occur only after^a flight
leaves source country. This may
preclude sending U.S. Customs
entry no. ~~to~~ the day before shipment
arrival. How will FDA address
and incomplete prior notice?
resulting from this limitation?
i.e. no U.S. Customs entry no.



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QUESTIONS FOR PANELISTS

Name: RAY GLOWAKY

Affiliation: CHOCOLATE MANUF. ASS'N.

FOR LONG RANGE, LONG TIME SHIPMENTS
IT MAY NOT BE POSSIBLE TO HIT THE
0-5 DAY WINDOW FOR PRIOR NOTICE
WHAT IF THE SHIPMENT ARRIVED
LATE MAKING NOTICE OVER 5 DAYS?



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QUESTIONS FOR PANELISTS

Name: Sam Glick

Affiliation:

1 How will FDA handle
Magallidora operations that
cross goods across the
border less than 24 hours
in advance, - often with only
hours notice?



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QUESTIONS FOR PANELISTS

Name: *Sam Gilsen*

Affiliation: *WTTC*

1. *How will FDA deal with
food shipments carried by Intermodal
transit under Bond?*
2. *How will FDA deal with goods
entering Foreign Trade Zones for
re-export?*



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QUESTIONS FOR PANELISTS

Name: SAM GILSON

Affiliation: WASH TARIFF/TRADE LETTER

WILL EACH PRIOR NOTICE GET ITS OWN

ID # FOR USE IN SUBMITTING

UPDATES OR WILL SUBMITTERS HAVE TO

RESEND EACH NOTICE IN TOTAL EACH

TIME THEY UPDATE?



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QUESTIONS FOR PANELISTS

Name: Rick Hernandez

Affiliation:

PLEASE explain the "TIME WINDOW"
when the prior notice must be sent.
The "DEFAULT" PERIOD IN THE BIOTERRORISM ACT
IS NOT FEWER THAN 8 HOURS AND NOT MORE
THAN 5 DAYS.



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QUESTIONS FOR PANELISTS

Name: SAM GILSTON

Affiliation: WASHINGTON TARIFF & TRADE LETTER

WHAT LIMITS, IF ANY, APPLY TO THE
NUMBER OF AMENDMENTS MADE TO
PRIOR NOTICES OF SHIPMENT?
TO WHAT EXTENT MUST EACH AMENDMENT
RECAPITULATE THE INFORMATION IN SUCH
NOTICES THAT DOES NOT CHANGE?



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QUESTIONS FOR PANELISTS

Name: SAM GILSON

Affiliation: Washington Tariff & Trade Letter

1. How will FDA & Customs coordinate
the receipt & acceptance of prior notice?
2. Will goods be subject to prior notice to
both FDA & Customs?
3. Will FDA & Customs computer systems
be linked and when?
4. Who at port - Customs or FDA - will
have responsibility to determine food
shipment can be imported in case of dispute?



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QUESTIONS FOR PANELISTS

Name: Ann Ungvarsky

Affiliation: Hogan + Hartson L.L.P

Will FDA be sharing ~~the~~ information provided under its
prior notice rule w/ APHIS (Animal + Plant Health Inspection Service)?

Does the following scenario comply with the prior notice requirements.
~~Can a~~ ~~Food~~ arrives
~~what if~~ ~~shipment~~ ~~be placed~~ in a foreign trade zone ^{on Monday} but
~~isn't~~ ^{with customs} entered until Tuesday & we provide notice ~~on~~ after
~~Monday~~ ^{the} it arrives in foreign trade zone but by noon
the calendar day before it is entered with customs, ~~does~~

~~These~~



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QUESTIONS FOR PANELISTS

Name: Robert Hahn

Affiliation: Olsson, Frank and Weeda

What if shipment contains
food grown on hundreds or
thousands of farms.

Must importers provide names
of all those farms, if
known?



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QUESTIONS FOR PANELISTS

Name: *Stephen Payne*

Affiliation: *Pet Food Institute*

*Is prior notice required ~~for~~ for
food/feed/ingredients for research use
only or for consumption by non-food
producing lab animals?*



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QUESTIONS FOR PANELISTS

Name: Pat O'Connor

Affiliation: International Warehouse Logistics Association

In the event prior notice is not submitted
or is inadequate

① Does FDA or Customs make the decision
to move the product to a secure facility

② what is meant by "secure facility,"
is this a ^{customs} bonded warehouse



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QUESTIONS FOR PANELISTS

Name: Donna Garver

Affiliation: United Fresh Fruit + Vegetable Assn

How will FDA interact with ~~the~~ Customs —

Will FDA regulations on prior notice supercede

U.S. Customs' 24-hr Rule on Prior Notice when

food articles are being imported



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QUESTIONS FOR PANELISTS

Name:

John Bode

Affiliation:

Dixon, Frank & Needa

Please explain why ~~so much~~
such a long period of prior
notice is being proposed. ~~is~~



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QUESTIONS FOR PANELISTS

Name: BOB EMMERSON

Affiliation: JOURNAL OF COMMERCE

DOES FDA PRIOR NOTICE REQUIREMENT

PRECLUDE U.S. CUSTOMS "24-HOUR RULE" FOR

ADVANCE NOTICE OF OCEAN-BORNE CARGO?



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QUESTIONS FOR PANELISTS

Name: John Conley

Affiliation: National Truck Truck Carriers

You mentioned that the prior
notice must include the
name of the carrier.

Are carriers of the food,
such as trucking companies or
railroads, required to register?
(Not addressed by first panel)



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QUESTIONS FOR PANELISTS

Name: Bob Procelli.

Affiliation: FoodTrace Inc. rprocelli@itmassociates.com

There is existing technology to issue certificates electronically.
For imports of organic foods in support of the similar
There is existing technology to electronically
issue certificates. Will the FDA develop its
own technology to support these requirements or will it
use commercially available software? For example there
is
already existing technology that meets similar
requirements under the Organic Food Production
Act.



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QUESTIONS FOR PANELISTS

Name: RAY GLOWAKY

Affiliation: CHOCOLATE MANUF. ASSN.

WHAT IF THE 'GROWER' IS NOT

KNOWN — FOR EXAMPLE, COCOA

BEANS FROM 50 SMALL FARMS?



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QUESTIONS FOR PANELISTS

Name: *John Maxwell*

Affiliation: *NABT*

*A container of imported wine
might contain 5 different size bottles
of the same wine from the same
mfg. Does a prior notice have to be
filed for each size.*



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QUESTIONS FOR PANELISTS

Name: Richard Koby

Affiliation: Cheese Importers Assoc.

What does FDA propose to do
with its ^(web-based) OASIS system once the
Prior Notice System comes on-line?



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QUESTIONS FOR PANELISTS

Name: Cheryl Brown

Affiliation: KRA Corp.

Will incoming shipments be held pending
some type of notification from FDA that
Prior Notice has been both received & approved?



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QUESTIONS FOR PANELISTS

Name:

Affiliation:

① Will prior notice be required
for samples from foreign suppliers
to U.S. companies for testing
& evaluation?

② Will FDA Inspectors now
be available on weekend days -
not just M-F? (at borders)



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QUESTIONS FOR PANELISTS

Name: Norma Skolnik

Affiliation: Adams Worldwide Division, Morris Plains N.J.
Pfizer Inc

How will detained materials be
handled if importer hasn't been able
to notify FDA ^{8 hours} in advance of material
arrival?



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QUESTIONS FOR PANELISTS

Name: Jennifer Couzin

Affiliation: Science Magazine

~~Is there anything that~~ What, if anything,
would lead you

to reject a shipment, other than a

failure to properly fill out the electronic form?



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QUESTIONS FOR PANELISTS

Name: Chris Brown

Affiliation:

PRIOR NOTICE:

What happens when the system
goes down - any provisions for business
to supply information in an alternate
manner